

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 07/402,450
Applicant : George J. MURAKAWA et al.
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TC/A.U. : 1637
Examiner : Surya Prabha Chunduru

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Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' REQUEST FOR REHEARING

Dear Sir:

In response to the Decision on Appeal dated 13 July 2011, Appellants hereby request rehearing under 37 § 41.52.

I. STATUS OF APPEAL

In the Decision on Appeal, the Board reversed (i) the Examiner's rejection of claims 190-192, 194, 195, 197, 199-201, 203, 204, 206, 208-210, 212, 213, 215, 217-219, 221, 222, 224, 242-245 and 249-255 under 35 U.S.C. §135(b)(1) based on Wang (Wang et al.; US 5,219,727) and (ii) the Examiner's rejection of claims 193, 196, 198, 202, 205, 207, 211, 214, 216, 220, 223 and 225 under 35 U.S.C. §135(b)(1) based on Wang and Mullis (Mullis et al.; US 4,683,195). Although the Board reversed both of the Examiner's rejections, the Board entered two new grounds of rejection under the provisions of 37 C.F.R. § 41.40(b).

First, the Board rejected claims 190, 199, 208, 217 and 249-255 on grounds that Appellants are estopped from claiming subject matter that is not patentably distinct from the count in Interference 105,555 citing *In re Deckler*, 977 F.2d 1449 (Fed. Cir. 1992) and *In re Kroegel*, 803 F.2d 705 (Fed. Cir. 1986). Second, the Board rejected claims 190, 199, 208, 217 and 249-255 on grounds of estoppel under 37 C.F.R. §1.658(c). The Board only applied these

rejections to the independent claims and suggested that, if prosecution is continued, the Examiner should consider (i) whether the dependent claims are patentably indistinct from the count in Interference 105,055 or (ii) whether Appellants also could have moved to add the dependent claims during the interference.

Appellants submit that the Board misapprehended or overlooked certain points discussed in detail below in entering the new grounds of rejection and request rehearing of these new grounds of rejection.

II. SUMMARY

Appellants respectfully submit that the Board's new grounds of rejections are contrary to Interference Board's holding in Interference 105,055. Following the Interference Board's holding that Murakawa's then-pending claims were barred by § 135(b) (decision on Wang preliminary motion 1), it ordered Murakawa to submit a single claim that Murakawa believed was not barred by § 135(b). In response, Murakawa filed Murakawa's Preliminary Motion No. 1 in which it submitted proposed claim 50 with a request that it be entered and designated as corresponding to the Count. The Interference Board denied Murakawa's motion on grounds that proposed claim 50 was patentably distinct from Wang's involved claims and there was, therefore, no interference in fact. Based on that ruling, Murakawa returned to *ex parte* prosecution to pursue the generic claims.

One of the features of Murakawa's claim 50 that led the Interference Board to rule that it was patentably distinct was that Wang's claim was limited to the use of a shared primer pair for the target and reference sequences, whereas Murakawa proposed claim 50 was generic and included reference sequences that could be PCR amplified with the same or different primer pairs. The Interference Board concluded that Murakawa's generic claim did not anticipate or render obvious Wang's claim to a shared primer pair because the language of Murakawa's claim ("at least one synthetic RNA sequence ... which includes substantially more nucleotides than said target sequence") encompassed a large number of species that would not be amplified with the same primer pair that amplifies the target sequence. There was never a dispute that the language would encompass a reference sequence including the target and an insert, such that it

would be amplified by a shared primer pair with the target, but the Interference Board held that the claim also included many other possible reference sequences that could only be amplified with different primer pairs and, therefore, one would not immediately envisage the shared primer pair of Wang from the generic claim of Murakawa. The Interference Board concluded that Wang's claim was neither anticipated nor obvious over Murakawa proposed claim 50, thus the two-way test for interference in fact was not met and the claims were patentably distinct. Thus, Appellants submit that the subject matter of 190, 199, 208, 217 and 249-255 is patentably distinct from the Interference Count for the very same reasons found by the Interference Board in considering the patentable distinctness of Murakawa proposed claim 50.

The subject matter of claims 190, 199, 208, 217 and 249-255 is similar in scope to the subject matter of Murakawa proposed claim 50 with respect to (a) the nature of the reference sequence, *i.e.*, both are a genus, and (b) encompassing the use of same primers or different primers. Since the subject matter is similar in these aspects, Appellants submit that such subject matter was submitted and raised in Interference 105,055. Alternatively, Appellants submit that the Order to submit a single interfering claim precluded Appellants from presenting other claims, including the instant claims on appeal.

III. CLAIMS 190, 199, 208, 271 AND 249-255 ARE PATENTABLY DISTINCT FROM THE COUNT IN INTERFERENCE 105,055

In reversing the Examiner's § 135(b) rejections, the Board concluded "[s]ince the claims on appeal expressly do not require or necessarily result in use of shared primer pairs to amplify the target and reference nucleic acid sequences, they are not directed to the same or substantially the same invention as claimed by Wang." Decision on Appeal, p. 4. The Board based this conclusion on the fact that "[a]ll of the claims on appeal recite that the target sequence and reference sequence 'can be amplified by the same or different oligonucleotides.'" *Id.* (emphasis added). In contrast to this conclusion,¹ the Board entered new rejections on grounds that the

¹ As a preamble to these statements, the Board summarized the determination of the Board in Interference 105,055 (hereinafter "Interference Board") as set forth in the Final Judgment (paper 48). According to the Board, the Interference Board "concluded that one of material limitations of Wang's claims was 'use of a shared primer pair for amplifying the control and target sequences,'" which limitation "was not part of the claims that had been filed by

subject matter of claims 190, 199, 208, 217 and 249-255 "is not patentably distinct from the count in Interference 105,055." Decision on Appeal, p. 5.

The Interference Board characterized the earlier Murakawa claims essentially as generic claims, *i.e.*, claims that encompass use of shared primer pairs or different primer pairs to amplify a target nucleic acid sequence and a control. In particular, the Interference Board determined that the earlier Murakawa claims 18, 19, and 30 do not require use of shared primer pairs. Decision on Wang preliminary motion 1, paper 36, p. 16-17. Also, the Interference Board determined that the earlier Murakawa claims 18, 19, and 30 do not require or necessarily result in use of shared primer pairs. Decision on Wang preliminary motion 1, paper 36, p. 17-23. The Interference Board ultimately held that "none of the earlier Murakawa claims, i.e. Murakawa claims filed or pending as of June 15, 1994 . . . are directed to the same or substantially the same invention as claimed in the Wang 1993 patent because, although they recite use of a predetermined initial amount of a control sequence, none require or necessarily result in use of shared primer pairs."² *Id.*, pp. 22-23 (emphasis added); see also p. 25.

The Interference Board characterized the reference sequence of Murakawa proposed claim 50³ as "a synthetic RNA sequence selected from one of two genera, *i.e.*, a reference sequence which does not include the target sequence or a reference sequence which includes substantially more nucleotides than the target sequence." Decision on Murakawa preliminary motion 1, paper 47, p. 9. Although Murakawa argued that the latter genus was small enough to

Appellants, or were pending, within one year of the issue date of the Wang patent," and therefore the Murakawa claims "are not directed to the same or substantially the same invention . . . because . . . none require or necessarily result in use of shared primer pairs." Final Judgment, paper 48, pp. 5, 13-23.

² The Board's reversal of the Examiner's rejection under 35 U.S.C. § 135(b)(1) in the current Decision on Appeal maintains that the generic claims are patentably distinct, *i.e.* do not claim the same or substantially the same subject matter as Wang et al., because the claimed subject matter does not require the use of a shared primer pair while the claims of Wang et al. do.

³ Murakawa proposed claim 50 is a claim that Appellants proposed to add to the instant application and to designate as corresponding to the Interference Count in response to an Order by the Interference Board. See Murakawa preliminary motion 1, paper 38, pp. 2-3.

anticipate a reference sequence which used a same primer pair as the target sequence, the Interference Board held otherwise: “[i]n view of this record and the testimony of Dr. Joyce cited above, we find that proposed Murakawa claim 50 would not have immediately suggested using a reference sequence which binds to the same primers as the target sequence in the same PCR amplification reaction mixture.” *Id.*, p. 21. The Interference Board further concluded that “[t]he definition of a reference sequence distinguishable from a target sequence by size is broad and general and does not particularly suggest a reference sequence which binds to the same primer pair as a target sequence.” *Id.* Although the Interference Board had previously held⁴ that the earlier Murakawa claims did not exclude the use of shared primer pairs, *i.e.*, the same primers, it determined that simultaneous amplification of the target sequence and the reference sequences of Murakawa proposed claim 50 was a genus and did not anticipate the use of the species of the same primers as required by Wang. *Id.*, pp. 15-23. The Interference Board also determined that Murakawa proposed claim 50 in combination with other prior art cited by Murakawa did not render obvious the species, *i.e.*, use of the same primers as required by Wang. *Id.*, pp. 23-29. Since Wang’s claim was patentably distinct over Murakawa proposed claim 50, the Interference Board held that there was no interference-in-fact. *Id.*, pp. 29-30. In view of this finding by the Interference Board, Appellants submit that the Interference Board found that Murakawa proposed claim 50 was patentably distinct from the Wang claim.

Appellants submit that the relevant parts of Murakawa proposed claim 50⁵ and the instant claims on appeal describe the same element, namely the use of same or different oligonucleotides, *i.e.*, primer pairs, to simultaneously amplify a target sequence and a reference sequence. Step (ii) of Murakawa proposed claim 50 recited

simultaneously subjecting a sample and a predetermined quantity of at least one synthetic RNA sequence to a polymerase chain reaction (PCR) amplification under conditions to simultaneously amplify a target sequence if present in the sample and the reference sequence.

⁴ See Decision on Wang preliminary motion 1, paper 36, pp. 16-17.

⁵ Murakawa proposed claim 50 was based on claim 27 of the instant application incorporating the limitations of claims 18 and 26 from which it depends. Murakawa preliminary motion 1, paper 38, p. 5.

The reference sequence in Murakawa proposed claim 50 either (a) does not include the target sequence or (b) includes substantially more nucleotides than the target sequence. Appellants submit that it was well known in the art at the priority date of the instant application that PCR amplification required the use of a primer pair to amplify a given sequence, whether a target sequence or a reference sequence. For the amplification of a target sequence and a reference sequence, the primer pair could be the same primer pair or could be different primer pairs. With respect to the subject matter of Murakawa original claims 18,⁶ 19 and 30, the Interference Board concluded that this subject matter encompasses the use of a shared primer pair. Decision on Wang preliminary motion 1, paper 36, p. 22. Furthermore, Murakawa proposed claim 50 also encompasses the use of a shared primer pair. See Murakawa Reply 1, paper 45, p. 12 and Decision on Murakawa preliminary motion 1, paper 47, p. 17. Specifically, the genus "synthetic RNA sequence . . . which includes substantially more nucleotides than the target sequence," encompassed a larger sequence that include the same 3' primer binding sites as the target sequence, but did not necessarily do so.

Claims 190, 199, 28, 217 and 249-255 all require the step of simultaneously subjecting a target sequence and a reference sequence to PCR amplification under conditions appropriate to simultaneously amplify the target sequence and the reference sequence. See, for example, step (iii) of claim 190. According to these claims, the reference sequence comprises a sequence present in the selected target viral RNA sequence and a sequence not present in the selected target viral RNA sequence. See, for example, step (ii) of claim 190. Appellants submit that

the reference sequence "which includes substantially more nucleotides than the target sequence"

of Murakawa proposed claim 50 represents a genus that is similar to the genus represented by

the reference sequence which "comprises a sequence present in the selected target viral RNA sequence and a sequence not present in the selected target viral RNA sequence"

of claims 109, 199, 208, 217 and 249-255. Also according to these claims the reference sequence and the target sequence can be amplified by the same or different primers. See, for

⁶ Murakawa original claim 18 is a basis for Murakawa proposed claim 50. (Murakawa preliminary motion 1, paper 38, p. 5)

example, step (ii) of claim 190. These claims merely recite the feature that the Interference Board held was encompassed by Murakawa's earlier claims and Murakawa proposed claim 50, i.e., use of the same primer pair. It is evident from a comparison of these claims with Murakawa proposed claim 50 that the instant claims specifically recite language that was, in material respect, the same as that in Murakawa proposed claim 50. That is, both Murakawa proposed claim 50 and the instant claims encompass use of a shared primer pair and use of different primer pairs, and thus both encompass a genus.

The earlier Murakawa claims, including Murakawa original claims 18, 19, and 30 and Murakawa proposed claim 50, were held by the Interference Board not to be the same or substantially the same invention as the Count of Interference 105,055, did not present an interference-in-fact (see Decision on Murakawa preliminary motion 1, paper 47, p.47), or were patentably distinct because Wang's claim was not anticipated or rendered obvious by Murakawa proposed claim 50. Appellants submit that, for consistency and conformity, the same result applies to the instant claims which merely specifically recite features that were in the Murakawa original claims and in Murakawa proposed claim 50 as applied in Interference 105,055. Accordingly, Appellants submit that claims 190, 199, 208, 217 and 249-255 are patentably distinct from the Count of Interference 105,055 for the very same reasons that the Interference Board found Murakawa proposed claim 50 patentably distinct from Wang's claim 1. Thus, Appellants request reconsideration and withdrawal of this new ground of rejection.

IV. CLAIMS 190, 199, 208, 271 AND 249-255 COULD NOT HAVE BEEN ADDED IN INTERFERENCE 105,055

According to the Board in the new ground of rejection based on estoppel under 37 C.F.R. §1.658(c), "[b]ecause Appellants could have moved to add newly rejected claims 190, 199, 208, 217, and 249-255 to their application during Interference 105,055 but failed to do so, they are 'estopped to take ex parte or inter partes action in the Patent and Trademark Office after the interference which is inconsistent with [their] failure to properly move,'" citing 37 C.F.R. § 1.658(c). Decision on Appeal, p. 14. Specifically, the Board points out that "[a]fter Wang filed its motion in the interference to have Appellants' claims held unpatentable under 35 U.S.C §

135(b), Appellants could have sought authorization to file a motion to add newly rejected claims 190, 199, 208, 217, and 249-255 to avoid the bar of § 135(b).” *Id.*

Appellants submit that interference estoppel under 37 C.F.R. §1.658(c) does not apply because the Board’s determination during the Interference that the earlier Murakawa generic claims (claims 1-12 of application 07/143,045 and claims 1-33 of application 07/402,450), encompassing use of shared primer pairs or different primer pairs to amplify a target nucleic acid sequence and a control, are not directed to the same or substantially the same invention as claimed in the Wang 1993 patent (corresponding to the Count) prevented Murakawa et al. from pursuing generic claims during the interference. Alternatively, Appellants submit that subject matter with similar elements was submitted in Interference 105,055. For either of these reasons, Appellants submit that estoppel under 37 C.F.R. § 1.658(c) does not apply.

The Interference Board characterized the earlier Murakawa claims essentially as generic claims, *i.e.*, claims that encompass use of shared primer pairs or different primer pairs to amplify a target nucleic acid sequence and a control. In particular, the Interference Board determined that the earlier Murakawa claims 18, 19, and 30 do not require use of shared primer pairs. Decision on Wang preliminary motion 1, paper 36, pp. 16-17. Also, the Interference Board determined that the earlier Murakawa claims 18, 19, and 30 do not require or necessarily result in use of shared primer pairs. *Id.*, pp. 17-23. The Interference Board ultimately held that “none of the earlier Murakawa claims, i.e. Murakawa claims filed or pending as of June 15, 1994 . . . , are directed to the same or substantially the same invention as claimed in the Wang 1993 patent because, although they recite use of a predetermined initial amount of a control sequence, none require or necessarily result in use of shared primer pairs.”⁷ *Id.*, pp. 22-23 (emphasis added); see also p. 25.

Appellants submit that interference estoppel under 37 C.F.R. §1.658(c) cannot apply here because the Interference Board’s determination during the interference that the earlier Murakawa generic claims are patentably distinct, *i.e.*, not directed to the same or substantially the same

⁷ The Board’s reversal of the Examiner’s rejection under 35 U.S.C. § 135(b)(1) in the current Decision on Appeal maintains that the generic claims are patentably distinct, *i.e.* do not claim the same or substantially the same subject matter as Wang et al., because the claimed subject matter does not require the use of a shared primer pair while the claims of Wang et al. do.

invention as the Wang patent corresponding to the count, prevented Murakawa from later⁸ adding generic claims pursuant to the Order that Murakawa submit a claim that interferes with the claimed subject matter. Order dated November 5, 2003, Paper 37; see MPEP 2301.03 ("A claim of one inventor can be said to interfere with the claim of another inventor if they each have a patentable claim to the same invention. The Office practice and the case law define "same invention" to mean patentably indistinct inventions. . . . If the claimed invention of either party is patentably distinct from the claimed invention of the other party, then there is no interference-in-fact."). By determining that the earlier Murakawa generic claims encompassing use of shared primer pairs or different primer pairs were patentably distinct from the count, the Interference Board effectively prevented Murakawa from adding the generic claims to the count and obtaining a judgment on the generic claims. The Interference Board effectively limited the scope of the interfering claimed subject matter to use of only shared primers.⁹ Thus, Appellants submit that estoppel under 37 C.F.R. § 1.658(c) does not apply.

Additionally, the Board's new ground of rejection under interference estoppel is based on the premise that each of the independent claims on appeal is directed to subject matter that is not patentably distinct from Count 1 in Interference 105,055 and relies on *In re Kroekel* and *In re Deckler*.

"the claims on appeal are directed to subject matter that includes the subject matter of the count in Interference 105,055 or is not patentably distinct from the subject matter of the count,"

Decision on Appeal, p. 12.

⁸ The Interference Board prevented Murakawa et al. from adding generic claims before its decision on the § 135(b) bar motion. See Murakawa List of Intended Preliminary Motions, Paper 20 (includes Rule § 633(c) Motion to redefine the interference by adding one or more claims to Murakawa's application to be designated to correspond to the count); Order Setting Times, Paper 24 ("A threshold issue, Wang preliminary motion 1, contending the Murakawa's involved claims are barred under 35 U.S.C. § 135(b), has already been placed on an expedited schedule. Time periods 1 through 8 are set and hereby suspended pending a decision on Wang preliminary motion 1. . . . No preliminary motions in addition to the motions to those agreed upon during the conference call may be filed during TIME PERIOD 1 without prior approval of an APJ.")

⁹ During the interference, claims 1-4 and 6-10 of Wang corresponded to Count 1; and claims 5-7, 10-12, and 15-18 of the Wang 1995 patent (US 5,476,774) corresponded to Count 1. The only other claim in Wang is dependent claim 5, which does not recite any further limitations regarding the primers. Other claims in the Wang 1995 patent (1-4, 6-9, and 13-14) also do not recite any limitations regarding use of different primers.

Moreover, *In re Kroekel* is distinguishable because Kroekel never sought broader generic claims during the interference. See *In re Kroekel*, 803 F.3d at 707 (“Kroekel never moved to substitute a broader count, believing that Comstock could not support a broader count.”) Here, during the interference, Murakawa argued that all of the material limitations of the copied claim necessarily occur in, or result from, the prior claims in order to avoid the § 135(b) bar by establishing invention prior to the Wang patent. The earlier Murakawa generic claim encompassing use of shared primer pairs and different primer pairs were at issue during the interference and the Interference Board determined that the generic claims were patentably distinct from the count, *i.e.*, not directed to the same or substantially the same invention as the Wang 1993 patent corresponding to the count. The Interference Board thereby limited the scope of the count to use of shared primers and prevented Murakawa from adding generic claims encompassed use of shared primers or different primers. Thus, Murakawa et al. is not estopped under 37 C.F.R. §1.658(c) from now claiming a generic claim encompassing use of shared primer pairs and different primer pairs were patentably distinct from the count.

In re Deckler is distinguishable because the losing party of the interference proceeding admitted that the claims were patentably indistinguishable from the claim involved in the interference and thus was not entitled to a patent covering claims that the party. See 977 F.2d at 1451.

Furthermore, Appellants could not have added the subject matter of claims 190, 199, 208, 217 and 249-255 to Interference 105,055 because the Interference Board determined that the Wang claims determined “the actual amount of target sequence by simultaneously amplifying the target nucleic acid sequence and a known amount of an added reference sequence with the same primer pair in a single reaction mixture.” Decision on Murakawa preliminary motion 1, paper 47, p. 29. The Interference Board determined that Murakawa’s proposed claim 50 determined “the ‘relative’ amount of target sequence in the original sample . . .” *Id.*, p. 11.¹⁰ The Interference Board concluded that the determination of the actual amount of target sequence was patentably distinct over determining the relative amount as set forth in Murakawa’s proposed

¹⁰ See also Decision on Murakawa preliminary motion 1, paper 47, p. 10: “proposed Murakawa claim 50 determines the relative quantity of target sequence present in the sample before amplification . . .”

claim 50. *Id.*, p. 29. Since a step of determining a relative amount of target is not the same or substantially the same as determining the actual amount, Appellants submit that they could not have added claims 190, 199, 208 and 217 which contain no quantitation step and claims 249-255 which contain a relative quantitation to Interference 105, 055. Thus, Appellants submit that estoppel under 37 C.F.R. § 1.658(c) does not apply. Accordingly, Appellants request reconsideration and withdrawal of this ground of new rejection.

Alternatively, Appellants submit that they did present subject matter similar to the subject matter of claims 190, 199, 208, 217 and 249-255 during the interference. Specifically, Appellants submit that the relevant parts of Murakawa proposed claim 50¹¹ and the instant claims on appeal describe the same element, namely the use of same or different oligonucleotides, *i.e.*, primer pairs, to simultaneously amplify a target sequence and a reference sequence. Step (ii) of Murakawa proposed claim 50 recited simultaneously subjecting a sample and a predetermined quantity of at least one synthetic RNA sequence to a polymerase chain reaction (PCR) amplification under conditions to simultaneously amplify a target sequence if present in the sample and the reference sequence. The reference sequence in Murakawa proposed claim 50 either (a) does not include the target sequence or (b) includes substantially more nucleotides than the target sequence. Appellants submit that it was well known in the art at the priority date of the instant application that PCR amplification required the use of a primer pair to amplify a given sequence, whether a target sequence or a reference sequence. For the amplification of a target sequence and a reference sequence, the primer pair could be the same primer pair or could be different primer pairs. With respect to the subject matter of Murakawa original claims 18,¹² 19 and 30, the Interference Board concluded that this subject matter encompasses use of a shared primer pair. Decision on Wang preliminary motion 1, paper 36, p. 22. Furthermore, Murakawa proposed claim 50 also encompasses use of a shared primer pair.

¹¹ Murakawa proposed claim 50 was based on claim 27 of the instant application incorporating the limitations of claims 18 and 26 from which it depends. Murakawa preliminary motion 1, paper 38, p. 5.

¹² Murakawa original claim 18 is a basis for Murakawa proposed claim 50. (Murakawa preliminary motion 1, paper 38, p. 5)

See Murakawa Reply 1, paper 45, p. 12 and Decision on Murakawa preliminary motion 1, paper 47, p. 17.

Claims 190, 199, 28, 217 and 249-255 all require the step of simultaneously subjecting a target sequence and a reference sequence to PCR amplification under conditions appropriate to simultaneously amplify the target sequence and the reference sequence. *See*, for example, step (iii) of claim 190. According to these claims, the reference sequence comprises a sequence present in the selected target viral RNA sequence and a sequence not present in the selected target viral RNA sequence. *See*, for example, step (ii) of claim 190. Appellants submit that the reference sequence “which includes substantially more nucleotides than the target sequence” of Murakawa proposed claim 50 is similar in scope to the reference sequence which “comprises a sequence present in the selected target viral RNA sequence and a sequence not present in the selected target viral RNA sequence” of claims 109, 199, 208, 217 and 249-255. Also according to these claims the reference sequence and the target sequence can be amplified by the same or different primers. *See*, for example, step (ii) of claim 190. It is evident from a comparison of these claims with Murakawa proposed claim 50 that the instant claims specifically recite language that was inherent in Murakawa proposed claim 50. That is, both Murakawa proposed claim 50 and the instant claims encompass use of a shared primer pair and use of different primer pairs, and thus both encompass a genus. Accordingly, Appellants request reconsideration and withdrawal of this new ground of rejection.

V. CONCLUSION

For the reasons discussed above, Appellants submit that the Board has misapprehended or overlooked those points discussed above in entering the new grounds of rejection. Appellants hereby request rehearing of these new grounds of rejection.

Respectfully submitted,

ROTHWELL, FIGG, ERNST & MANBECK, p.c.

By /Jeffrey L. Ihnen/

Jeffrey L. Ihnen
Registration No. 28,957
1425 K Street, N.W., Suite 800
Washington, D.C. 20005
Telephone No.: (202) 783-6040
Facsimile No.: (202) 783-6031